HED DOC. NO. 013287

30-MAR-1999

MEMORANDUM

SUBJECT: ***PHOSTEBUPIRIM*** **-** Report of the FQPA Safety Factor Committee

The FQPA safety factor recommendation in this report supercedes that previously reported for phostebupirim in the FQPA SAFETY FACTOR RECOMMENDATIONS FOR THE ORGANOPHOSPHATES dated August 6, 1998.

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FQPA Safety Factor Committee
Health Effects Division (7509C)

THROUGH: Ed Zager, Chairman
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PC Code: 129086

The FQPA Safety Factor Committee met on March 29, 1999 to reevaluate the hazard and exposure data for phostebupirim, and recommended that the FQPA Safety Factor (as required by Food Quality Protection Act of August 3, 1996) be removed (1x) in assessing the risk posed by this chemical. The FQPA safety factor recommendation in this report supercedes that previously reported for phostebupirim in the *FQPA SAFETY FACTOR RECOMMENDATIONS FOR THE ORGANOPHOSPHATES* dated August 6, 1998.

I. HAZARD ASSESSMENT

A. Adequacy of the Toxicology Database

The toxicology database is adequate for phostebupirim according to the Subdivision F Guideline requirements for a food-use chemical.

B. Determination of Susceptibility

Prenatal developmental toxicity studies in rats and rabbits provided no indication of increased susceptibility of rat or rabbit fetuses to *in utero* exposure to phostebupirim. There was no indication of increased susceptibility in the offspring as compared to parental animals in the two generation reproduction study. In these studies, effects in the fetuses/offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

C. Determination of Developmental Neurotoxicity Study

There are sufficient data available to adequately assess the potential for toxicity to young animals following pre-and/or post-natal exposure to phostebupirim. These include acceptable developmental toxicity studies in rats and rabbits, as well as, a 2-generation reproduction studies in rats. In addition, no treatment-related neuropathology was seen in studies conducted in hens and rats. Based on the weight-of-evidence, the HIARC determined that a developmental neurotoxicity study in rats is not required.

II. EXPOSURE ASSESSMENT AND RISK CHARACTERIZATION

A. Dietary Exposure Considerations

Phostebupirim is an insecticide used to control soil-dwelling insect pests in corn. One in-furrow or band incorporated application is made to soil at the time of planting. Time-limited tolerances (expiration date: July 6, 1999) have been established for phostebupirim *per se*, in/on corn (sweet, grain, field, and pop) at 0.01 ppm (40 CFR §180.483). Corn is considered to be a food which is highly consumed by infants and children (1993 NAS report, Pesticides in the Diets of Infants and Children).

Residue data sources available for phostebupirim include field trial data and processing studies submitted to the Agency. No monitoring data or information on percent of crop treated (%CT) are available for this pesticide.

The acute and chronic dietary exposure analyses for phostebupirim are unrefined, making the conservative assumption that all corn products contain residues at the level of tolerance. In general, this Tier 1 approach results in an overestimate of dietary exposure (although in this case the estimate may only be slightly exaggerated since the tolerance is established at the very low level of 0.01ppm).

B. Drinking Water Exposure Considerations

At the time of the meeting, the environmental fate database for phostebupirim was incomplete (unresolved issues with field dissipation studies). Based on the available data, the parent compound appears to be quite persistent and immobile in soil. The OMAT metabolite, however, appears to be quite mobile.

No monitoring data for phostebupirim are available. Therefore, environmental fate data were used in the following screening level models to calculate the estimated environmental concentrations (EECs): GENEEC (Tier 1) model for surface water; and SCI-GROW (Tier 1) for ground water.

The GENEEC model was used in conjunction with the available environmental fate data to calculate Tier 1 Estimated Environmental Concentrations (EECs) for dissolved residues of pesticide in surface water. GENEEC provides an upper bound on the concentration of pesticide that can be found in drinking water. If a risk assessment based on GENEEC does not exceed the level of concern, then the actual risk is not likely to be exceeded.

SCI-GROW (Screening Concentrations in Ground Water) is a model for estimating concentrations of pesticides in ground water under conditions of maximum exposure. SCI-GROW provides a screening concentration or an estimate of likely ground water concentration if the pesticide is used at the maximum allowed label rate in areas with ground water that is exceptionally vulnerable to contamination. In most cases, a majority of the use area will have ground water that is less vulnerable to contamination than the areas used to derive the SCI-GROW estimate.

C. Residential Exposure Considerations

Phostebupirim is not currently registered for residential uses.

III. SAFETY FACTOR RECOMMENDATION AND RATIONALE

A. Recommendation of the Factor

The Committee recommended that the FQPA safety factor be **removed (1x)**.

B. Rationale for Removing the FQPA Safety Factor

The Committee concluded that the safety factor could be removed for phostebupirim because:

1. The toxicology database is adequate for phostebupirim.

2. There is no indication of increased susceptibility of rat or rabbits to

phostebupirim. In the developmental and reproduction toxicity studies, effects in the fetuses/offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

3. The HIARC determined that a developmental neurotoxicity study in rats is not required..

4. Adequate actual data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary exposure and to provide a screening level drinking water exposure assessment (there are no registered residential uses for phostebupirim).